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Pharmaceutical Regulatory
and Compliance Seminar
Philadelphia, PA
November 2002

Responding to Enforcement Initiatives©

I. A Provider's Legal Obligation to Self-Report

A. The federal government maintains that Medicare prohibits providers from retaining payments to which they are not entitled, even if the provider discovers it is not entitled to the payment after it received the money. (42 U.S.C. § 1320-a7b(a)(3))

B. When billing Medicare for certain services, a provider may have to attest that it has complied with all Medicaid laws. Thus, the government argues that violations that do not directly affect reimbursement - - i.e. Stark, licensing requirements - - may still trigger an obligation to refund payment. See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 126 F.2d 899 (5th Cir. 1997) (claims submitted in violation of regulatory requirements actionable under False Claims Act only if claimant's certification of regulatory compliance is prerequisite for payment); United States ex rel. Hopper v. Anton, 91 F.3d 1261 (9th Cir. 1996) (mere regulatory violations do not give rise to FCA liability); United States ex rel. Windsor v. Dyncorp. Inc., 895 F. Supp. 844 (E.D. Va. 1995) (same).

C. False Claims Act (31 U.S.C.§§3729 (a)(1-7)(A-C))

1. FCA self-disclosure provision allows for double damages where:

   a. The provider discloses within 30 days of first obtaining information about the false claim;

   b. The provider cooperates fully with the investigation; and

   c. There is no existing government criminal prosecution, or civil or administrative action, and the provider did not have actual knowledge of the existence of an investigation.

2. The government may claim that it has the discretion to reject or accept a provider into the FCA self-disclosure program.

3. Mechanics of Disclosure

a. Must the provider disclose to the DOJ or will DOJ recognize a provider's disclosure to the OIG or intermediary?

b. When does DOJ start counting the 30 day period? From the date any employee learned of the facts, or just when "innocent management" learned? How much information starts the clock ticking?

D. Medicare carriers and intermediaries must report all suspected fraud to the OIG for its review, regardless of the amount of money involved or subject matter. See HCFA Transmittal No. AB-98-77.

E. OIG Voluntary Disclosure Program

1. In 1995 the OIG initiated a limited self-disclosure program as part of Operation Restore Trust ("ORT"). Providers did not perceive there were many benefits to it and only a few participated in it. The OIG ended this program in 1997.

2. The OIG announced a new voluntary disclosure protocol in October 1998.

a. It is open to all providers.

b. Disclosures must be submitted in writing to the OIG in Washington, D.C.

c. Written disclosures must include:

(i) identity of provider,

(ii) statement of whether the matter is presently under review/investigation by federal government,

(iii) a full description of issue giving rise to need for disclosure,

(iv) a description of how the matter affects the government,

(v) a description of why the matter may have violated federal l law, and

(vi) certification that the disclosure is accurate and made in good faith to resolve any potential liabilities with the government.

d. The OIG gives no advance commitments on how it will resolve a disclosure. There are no limits on the sanctions it can impose.

II. How You Will Find Out There is an Ongoing Government Inquiry

A. Government agencies that conduct most healthcare investigations:

1. U.S. Department of Justice/U.S. Attorney

2. Office of Inspector General, Department of Health and Human Services

3. Federal Bureau of Investigation

4. Internal Revenue Service

5. U.S. Postal Inspectors

6. State Medicaid Fraud Control Unit

7. Medicare Intermediary

8. State Boards that Oversee Doctors, Nurses, etc.

B. Employees may notify you that a government agent contacted them.

- You should consider having your Compliance Plan/Code of Conduct remind employees that the Company cooperates with all governmental investigations and requests that the employees do likewise; however, because it is vital that such cooperation occur in a coordinated manner. Consider requesting that all employees report to the Company any governmental investigations of which they become aware.

C. Customers, vendors, bankers, or other third parties may inform you of a government inquiry.

D. You may receive a request for documents.

1. The federal government issues three basic kinds of subpoenas in healthcare cases:

- Grand jury subpoenas for criminal investigations,

- DOJ subpoena under the Health Insurance Portability and Accountability Act of 1996 (18 U.S.C. § 3486) for criminal investigations but the information can also be shared with civil investigators, and

- Inspector general or administrative subpoenas.

2. The DOJ may issue a Civil Investigative Demand (31 U.S.C. § 3733) in civil investigations.*

3. The agency may send a letter request, which usually denotes a civil investigation.

4. The government may conduct a surprise or scheduled on-site visit to inspect records. Your Medicaid or Medicare provider agreement may require your cooperation.

5. Carrier/Intermediary Audit – This is a review for repayment, without any damages or government-imposed corporate integrity agreement. See Appendix G for an example.

E. Government agents may execute a search warrant in a criminal investigation.

- This is a very serious event and may signal that the government has a concern about the destruction of records and/or it believes that there is evidence of widespread criminal activity. In any event, this will seriously disrupt your every day business activity.

III. What To Do If You Find Out There Is A Government Inquiry/Investigation

A. Have legal counsel contact the government agent/attorney in charge of the investigation. Do not ignore it and hope that it goes away. Ask the factual and legal theory for the investigation. Indicate that you will cooperate to assist with the investigation. Get the citations to the specific statutes or regulations that the government claims you violated.

B. If this is a criminal investigation, ask if you are a target, subject, or witness, and have the government confirm this in writing. See Appendix A for definitions of these terms.

C. Hire outside counsel experienced in criminal/fraud and abuse matters.

- local counsel vs. regular outside counsel

- criminal attorney vs. healthcare attorney

Until you have reason to believe otherwise, treat all government investigations as potential criminal matters.

* Civil investigations can turn into criminal ones depending upon the evidence and the government's exercise of its discretion.

For those of you with in-house counsel, it is important that the in-house counsel play an active part with outside counsel in representing your Company. Depending upon the circumstances, in-house counsel may want to be present during the interview process and should be part of the decision making process. For those facilities/operators that do not have in-house counsel, someone from the operations side of the business may want to be present during the interview process, and should be a part of the decision making process.

IV. Mounting a Defense

A. Employees and former employees

1. Government Interviews - For Guidelines, see Appendix B

- Do not tell the employees they should not discuss the investigation with anyone. If they take you literally, and then tell the government that you told them not to speak, the government may view this as obstruction of justice. See 18 U.S.C. .§ 1518, Appendix C. Because you are not their attorney, you cannot tell them to talk to the government or not talk to the government.

- Should the employee insist on the government giving them a proffer letter (Appendix D) or immunity?

2. Do you offer to hire separate counsel for your employees and former employees?

- If yes, one attorney can initially represent all employees until and unless a conflict of interest arises. Clients can waive conflicts if they do so knowingly and freely, and the attorney can still effectively represent them. See, e.g. Ethical Rules of the Massachusetts Supreme Judicial Court, DR 5-105(C).

- Check your Articles/Bylaws and the laws of your Company's state of incorporation concerning your ability/duty to reimburse expenses to your employees, to advance payment for such expenses, and to demand repayment.

- Though the government may contest the position, there is strong legal authority for the company to assert that the government may not contact current company employees without the permission of the company's attorney. See United States ex rel. O'Keefe v. McDonnell Douglas Corp., 1998 U.S. App. Lexis 55 (8th Cir. Jan. 6, 1998).

3. Joint Defense Agreements

If the Company, its employees, or a third party are the focus of the investigation, all of them can enter into a Joint Defense Agreement that will allow the parties to share information but yet retain the attorney-client privilege for such shared information. Though the benefits of such an arrangement are obvious, some prosecutors greatly dislike joint defense agreements and may argue that such an agreement is evidence of lack of cooperation by the Company.

a. There are written and oral agreements. See Appendices E and F for examples of written agreements.

b. Joint defense agreements are binding and enforceable. See United States v. Weissman, 94 Cr. 760 (CSH), 1996 U.S. Dist. LEXIS 19036 (S.D.N.Y. Dec. 26, 1996) (enforces secrecy provision of joint defense agreement)

4. Company Interviews of Employees

a. Company lawyer is not the employees' lawyer

- Make certain that you tell the employees that the Company's attorney is not their attorney, that he or she does not represents them but represents the Company and the only attorney-client privilege between any employees and the Company's attorney is the Company's privilege.

b. Try to minimize employee gossip/speculation

c. Time pressures to conduct internal interviews

- Employee departures
- Government interviews
- Need to learn factual background

d. Whistle blowers

- No retaliatory firing
- Whistle blower must comply with employment obligations

5. Control access to your client/corporation's documents, tangible property, and real property

B. Develop the legal theories of your defense

- Involve Reimbursement and/or Healthcare Expert fully. Government investigators frequently lack healthcare expertise and may not fully understand the rules they are seeking to enforce.

C. Scope of Investigation

1. Internal investigation

You should immediately begin an internal investigation of the same issues the government is investigating and, if at all possible, at a faster pace than the government investigation. You need to:

- Quickly determine whether you have any potential liability.
- Discover facts that are favorable to you.
- Know what the facts are if, at a later date, you decide to engage in settlement discussions.

Most of the time, the government will tell you generally what it is investigating. If not, you can make an educated guess by interviewing employees and/or from the scope of the document request/search warrant.

- If the government investigation is directed at one facility, ideally you should expand your investigation to include other facilities that have similar facts/characteristics (e.g., if the alleged wrongdoing is due to a regional policy, in all likelihood, the government will make at least a cursory investigation of some or all of the facilities in that region).

2. Maintain the attorney-client privilege.

a. Communication to or from attorney

b. Seeking legal advice

c. Intended to be confidential

d. Reports to board of directors, high-level management

3. Do you want a written work product from the internal investigation?

- Government investigators frequently pressure companies to disclose the written work product from the internal investigation and waive privileges, as part of cooperating.

4. Retaining experts

a. Types

i. Billing/Audit

ii. Medical – No Hired Guns

iii. Forensic

iv. Public Relations

b. Maintain attorney-client privilege

5. Voluntary Disclosure to government?

V. Document Production

A. How to respond to subpoenas and Civil Investigative Demands

1. Is the request too broad? Do you educate the government about your Company in order to convince them to limit the request?

2. Do you challenge it in Court?

- Home court advantage

- Usually 20 day deadline to challenge CID

3. Do you refuse to comply and await motion to compel?

4. Normally, you will agree to produce records.

- Assuming that you have received a subpoena or other request for documents, immediately begin to determine how many documents are encompassed by the request.

- As a rule of thumb, you will under-estimate the amount of documents that you will need to produce and the effort and time that it will take to fully comply. Also, in all probability, the date for submission of the documents will not allow you adequate time. Call the government attorney after your initial review of the subpoena or the responsive documents to request more time to respond. It is far easier to receive an extension of time in which to produce documents than it is to negotiate a reduction in the types of documents to be produced.

- Be inclusive rather than exclusive in gathering requested documents. Do not make an independent decision that, even though the subpoena requests all documents of a certain category, "surely the government

isn't interested in these documents." If you do not want to produce certain documents because they are irrelevant to the investigation, discuss the matter with your attorney and the government first.

B. Document Retention Policy

1. Was the pre-investigation procedure adequate?

2. Review your procedures once the investigation has started.

If, for example, one for your facilities has received a subpoena for documents, send the administrator/executive director of the facility (and perhaps others) instructions on retention of documents pending the completion of the government investigation.

- All document destruction should immediately cease, even those that are in the normal course of business, without approval from the Company's attorney.

- Documents should not even be moved from one location to another without such approval.

VI. Disclosing Existence of Investigation

A. Regulatory Agencies

1. SEC

2. Other Regulators

B. Shareholders

- If you are a publicly traded company, you must make a decision if and when to publicly close the existence of a governmental investigation. Not all government investigations need to be disclosed.

C. Employees

- Once a subpoena is received, and once you begin to gather documents and/or begin your internal investigation, it is very difficult to prevent your employees from finding out. Rumors will be rampant. Thus, the question of whether, when and how to disclose the investigation to your employees (and perhaps to referral sources, families, etc.) needs to be considered.

D. Media Strategy

VII. Maintaining Credibility

A. Isolate the disputed issue from the rest of the Company.

1. During what time did the problem occur?

2. What is the scope of the problem?

3. What are the number and level of employees involved?

4. Establish the credibility of management.

- You will want to show the government how effective the Company compliance plan has been in avoiding problems. The issue the government is investigating is, at worst, an aberration that does not reflect the compliance-oriented corporate culture.

5. Always maintain the credibility of defense counsel.

B. Cooperation with the Government Investigation

- If for no other reasons than the government's vast resources and enormous power (including the ability to effectively put you out of business), you may want to indicate your willingness to cooperate with the government investigation immediately. In addition to the above negative reasons to cooperate, there may be benefits in cooperating. First, cooperation may lead to a quicker resolution of the investigation. Given the disruption to your business that an investigation will cause, a quick resolution is extremely beneficial. Second, you probably know more about health care than the government investigators. You may be able to point out certain favorable aspects (e.g., government suffered no actual harm) relating to the issues they are investigating. Finally, many government investigations result in negotiated settlements. In all probability, there is a better chance of a fair settlement if you have cooperated than if you have not.

VIII. Investigations Other Than Fraud and Abuse

Though most people associate government investigations with fraud and abuse, there has been an increase in investigations concerning quality of care outside the customary Health Department licensure/certification/complaint surveys and investigation process. This will grow as states pass laws which specifically criminalize elder abuse and neglect and prosecutors begin to familiarize themselves with such laws. See United States v. GMS Management – Tucker, Inc., et al., No. 96-1271 (E.D. Pa. 1996) (nursing home settles FCA liability arising from inadequate care to patients).